

Drug Safety Institute Comments

FDA PDUFA IV Public Meeting February 16, 2007

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1. Guidances to Industry

- Essential to industry, public and the Agency for establishing best practices & minimizing medication errors
- Pleased with Agency commitment to publishing the 3 guidances
- Encourage definitive timeline of 24 months after PDUFA IV implemented to publication of FINAL documents
- Critical to success of pilot program shifting name testing responsibility from FDA to Industry

1. Guidances to Industry (continued)

- Encourage Agency to expand guidance scope to include all FDA-regulated product proprietary names including:
 - vaccines, blood products, medical devices, veterinary drugs, OTC products
 - also include proprietary names under which distributors/repackers market approved products

2. Review Performance Goals

- Encourage target performance goal of 90 days for completing reviews of both INDs and NDAs
- Regarding proposed phase-in percentage of submissions subject to goal (50% year one, 90% year four or program):
 - Request clarification on how Agency will:
 - determine completion of 50% to 90% of workload
 - assimilate current backlog into the PDUFA IV review process

2. Review Performance Goals

(continued)

- Encourage Agency to adopt 90-day performance goal as timeline for not only review, but also notification of applicant as to review outcome

3. Pilot Program

- Commend FDA proposal to develop and implement pilot program shifting risk assessment & testing responsibility for proprietary names from FDA to Industry
- Consistent with FDA role of reviewing submitted data
- Suggest FDA set a timeline for pilot program implementation that coincides with publication of final 3 guidance documents (i.e. 24 months after PDUFA IV implemented)

3. Pilot Program (continued)

- Suggest pilot program be open to both INDs and NDAs
- Suggest Agency consider incentive, such as shorter review times, to get Industry to participate
- Suggest pilot be open to all pharmaceutical and consulting companies who routinely perform risk assessments

Thank You!